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AccuVert[™] HIV-1 Seroconversion Panel 0600-0291 / Batch #10602862

OVERVIEW

AccuVert[™] HIV-1 Seroconversion Panel 0600-0291 / Batch #10602862 is a 5-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial) collected from an HIV-1 donor. Panel members represent serial bleeds collected from a single donor over 17 days in 2000 during the development of an HIV infection and subsequent response. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HIV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a change of expression from negative to positive for HIV-1 antigen and antibodies during the development and progression of an HIV infection.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. LGC/SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for markers of HIV infection; all were found negative for HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens.

10,000,000 250.00 HIV-1 p24 Antigen 1,000,000 200.00 HIV Antigen/Antibody Signal to Cut-off (S/CO) 100,000 Copies per mL (c/mL) HIV-1 RNA HIV-1 Ag and Ab 150.00 10,000 1.000 100.00 100 50.00 10 0.00 1 2 6 0 8 10 12 14 16 **Days Since First Bleed**

AccuVert™ HIV-1 Seroconversion Panel

This graph demonstrates the evolution of early HIV infection amongst panel members from the Perkin Elmer (HIV-1 p24 Antigen), Abbott ARCHITECT (HIV-1 Antigen/Antibody), and Roche COBAS (HIV-1 RNA) test methods.

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Panel Member Information

Panel Member	SeraCare Batch #	Bleed Date	Days Since 1st Bleed	Fiebig Stage ¹
01	9118512	21-Mar-2000	0	NA
02	9118511	23-Mar-2000	2	NA
03	9118510	28-Mar-2000	7	I
04	9118509	30-Mar-2000	9	l
05	9118508	07-Apr-2000	17	II

¹ Fiebig stages are categories that define phases of early HIV infection. See Fiebig EW, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. AIDS 2003, 17:1871-9, and Lee HY, et al. Modeling sequence evolution in acute HIV-1 infection. JTB 2009, 261:341-360.

NA = Not Available

HIV RNA and HIV Antigen Assays

	Roche COBAS®				
	AmpliPrep/COBAS [®] TaqMan	PerkinElmer			
	HIV-1 Test v2.0	HIV-1 p24 ELISA			
Panel Member	(copies/mL) ¹	(S/CO) ¹			
01	TND	0.15			
02	TND	0.17			
03	9.61 x 10 ²	0.19			
04	1.65 x 10⁴	0.40			
05	>1.00 x 10 ⁷	>64.52			
Test Date	14-Mar-2022	15-Mar-2022			
Test Site	RL	SC			
Kit Part Code	NA	NEK050A			
Kit Lot No.	H22933	990-22041			
Kit Exp. Date	30-Apr-2023	1-Nov-2022			

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

TND=Target Not Detected

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SC = SeraCare; RL = Reference Lab; NA = Not Available



HIV Antigen/Antibody Assays

Panel Member	Abbott ARCHITECT	Abbott Alinity s	Roche Elecsys (Co	Ortho VITROS	
	HIV Ag/Ab Combo (S/CO) ¹	HIV Ag/Ab Combo (S/CO) ¹	HIV-1 p24 Ag	HIV-1/2 Ab	HIV combo (S/CO) ¹
01	0.10	0.07	0.16	0.09	0.11
02	0.08	0.07	0.16	0.09	0.11
03	0.10	0.09	0.18	0.09	0.12
04	0.28	0.24	0.44	0.09	0.25
05	225.56	205.3	373.00	0.09	373.50
Test Date	7-Mar-2022	4-Mar-2022	24-Mar-2022		10-Mar-2022
Test Site	SC	RL	RL		RL
Kit Part Code	2P36	NA	NA		NA
Kit Lot No.	34163BE00	311914BE00	557282		0360
Kit Exp. Date	7-Jul-2022	29-Aug-2022	31-Oct-2022		12-Jan-2023

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

HIV Antigen/Antibody, HIV Antibody Assays

Panel Member	Bio-Rad GS HIV-1/HIV-2 PLUS O EIA (S/CO) ¹	Avioq HIV-1 Microelisa System (S/CO) ¹	Siemens ADVIA Centaur [®] HIV Ag/Ab Combo (Index) ¹
01	0.09	0.24	<0.05
02	0.13	0.24	<0.05
03	0.13	0.25	<0.05
04	0.11	0.25	0.19
05	0.96, 1.03 *	0.26	>12.00
Test Date	9-Mar-2022	8-Mar-2022	7-Mar-2022
Test Site	SC	SC	RL
Kit Part Code	32588	100384	NA
Kit Lot No.	156RBB-05	21104H	308
Kit Exp. Date	30-Apr-2022	2-May-2023	30-May-2022

¹Results are reported as the mean result of duplicate testing.

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^{*}Interpretation variability based on duplicate testing, individual replicates reported.

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HIV Rapid Tests					
_	Alere Determine™ HIV-1/2 Ag/Ab Combo¹		OraSure OraQuick Advance [®] Rapid HIV-1/2 Antibody Test ¹		
Panel Member	HIV Ag	HIV Ab	HIV-1/2 Ab		
01	NEG	NEG	NEG		
02	NEG	NEG	NEG		
03	NEG	NEG	NEG		
04	NEG	NEG	NEG		
05	POS	NEG	NEG		
Test Date	3-Mar-2022		14-Mar-2022		
Test Site	SC		SC		
Kit Part Code	7D2648		1001.0079		
Kit Lot No.	167412		0006684580		
Kit Exp. Date	28-Jan-2023		31-Aug-2023		

¹Results are reported as singlicate testing; positive/reactive results are noted in bold red.

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SC = SeraCare

POS = Positive; NEG = Negative



HIV Confirmatory Assay

	Bio-Rad Genetic Systems™ HIV-1 Western Blot¹			
Panel Member	Band Pattern	Interpretation		
01	No Bands	NEG		
02	No Bands	NEG		
03	No Bands	NEG		
04	No Bands	NEG		
05	No Bands	NEG		
Test Date		8-Mar-2022		
Test Site		SC		
Kit Part Code		32508		
Kit Lot No.		64456713		
Kit Exp. Date	1-Sep-2022			

¹Results are reported as singlicate testing.

SC = SeraCare

NEG = Negative

HIV Confirmatory Assay (continued)

Panel Member	INNOGENETICS [®] INNO-LIA™ HIV I/II Score¹ Band Results							
	01	NEG	-	-	-	-	-	-
02	NEG	-	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-	-
04	NEG	-	-	-	-	-	-	-
05	NEG	-	-	-	-	-	-	-
Test Date	15-Mar-2022							
Test Site	RL							
Kit Part Code	NA							
Kit Lot No.	409067							
Kit Exp. Date				31-Aug-20)22			

¹Results are reported as singlicate testing. RL = Reference Lab; NA = Not Available NEG = Negative

The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at CDx-Info@LGCGroup.com or by phone at 508.244.6400.

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